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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,570	02/08/2002	Gijsbertus Johannes Van Oorschot	F7590(V)	1952

201 7590 09/27/2007

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EXAMINER	
WEBMAN, EDWARD J	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
09/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/072,570	VAN OORSCHOT ET AL.	
	Examiner	Art Unit	
	Edward J. Webman	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

After a patentability conference on 7/16/07, a consensus was reached to continue prosecution. Hence, the following rejection:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mezaache et all in view of Kelly et al, Giese et al, and the Merck Index.

Mezaache et al teach oral dosage forms (abstract). Lozenges are specified (column 2 line 41). Antiicholesterolemics, including lovastatin, are disclosed (column 8 lines 8-9). Gelatin is specified as a binder (column 12 line 34). 80-90% active is disclosed (column 3 lines 5-6).

Kelly et al teach genistein for the treatment of hypercholesterolemia (abstract). A daily dose of 50-150 mg is specified (column 9 line 67). After ingestion of the glucone form in humans, formation of genistein by hydrolysis is disclosed (column 6 lines 47-57).

Giese et al teach compositions for inhibiting protein kinases (title). Genistein is specified (column 8 line 46). Candies are disclosed (column 10 line 15).

The Merck Index teaches that lovastatin was isolated from *Monascus ruber*. It and genistein have been synthesized.

It would have been obvious to one of ordinary skill to add genistein to the composition of Mezaache et al to achieve the beneficial effect of a second anticholesteremia in view of Kelly et al and, in particular, to the lozenge in view of Giese et al. As to the claimed Hue a* value, synthetic lovastatin and genistein are well-known in the art in view of the Merck Index; it would be obvious to one of ordinary skill to use synthetic actives to maximize their purity. As to the claimed percentages of genistein versus genistin, the glucone form of genistein, optimum suitable percentages may be obtained by routine experimentation, given that Kelly et al teach a suitable dosage range of genistein and that the glucone form may be viewed as a delayed release form of genistein. Similarly, Mezaache et al teach a percent range of active; an optimum suitable dose of lovastatin may be determined by routine experimentation as well. As to the claimed extraction of the claimed actives from a fermentation product using the claimed extraction oil, such is a method of making which is not considered a patentable limitation in composition claims prosecuted before the USPTO.

Claims 11-28 are objected to because of the following informalities: In claim 19 "monascus" should be capitalized and both the genus and species be placed in italics. Appropriate correction is required.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number

is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDWARD J. KIMLIN
PRIMARY EXAMINER
GROUP 1600